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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,487	01/07/2002	Spiros Fotinos	366325-509	3570

25561 7590 10/20/2004

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,487	FOTINOS ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8 and 10-22* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 07/19/04. Claims 1-8 and 10-22 are pending. Claims 20 and 21 are amended.

Claim Rejections - 35 USC § 102

1. Claims 1-4, 6-8, 20 and 22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lorenz et al. (US 5,420,197).

Applicants' argument:

A) Claimed invention is a single uniform layer delivery disc of a filmogenic polymer that is non-tacky and dissolves onto a wetted skin tissue or mucosal epithelial tissue of a subject when applied thereto.

B) "Dissolution of the delivery disc on the wetted skin tissue or mucosal tissue is an integral property of the invention and must be addressed by the prior art rejection."

C) Lorenz discloses chitosan gel, which are highly water absorbent, stable and because are stable, they maintain their physical integrity after absorbing large quantities of liquid; Lorenz teaches that the gels are used as absorbent wound packing agents that become saturated with wound exudates and the gels of Lorenz are used as face masks that can be easily peeled off after use and that Lorenz provides specific examples wherein the gels are formed that do not dissolve or disintegrate. In example 5, Lorenz applies the gel to wet human skin and peels or rolls it off the skin. Furthermore, Lorenz discloses that the gel does not dissolve in large amounts of liquid, which is reiterated in example 6.

D) Based on the full disclosure, Lorenz fails to disclose a delivery disc that dissolves onto a wetted skin and thus does not teach each and every element of the claims.

2. Applicants' arguments filed 07/19/2004 have been fully considered but they are not persuasive.

In points A-D, the recurring issue is that the gel of Lorenz does not dissolve and applicants conclude that because the gel does not dissolve, Lorenz does not teach each and every element of the claims and thus the rejection should be withdrawn and insists that the art rejection must address the integral property of the invention.

Generic claim 1 is directed to a broad delivery disc that comprises a dry uniform mixture a filmogenic polymer and an effective dose of an active agent. This is the composition of the delivery system/disc. The generic claim fails to specify any polymer. The generic claim fails to specify active agent and effective dose. Regarding the active agent and effective dose, any active agent meets the limitation of the recited "active agent" and any dose of an active agent is effective and meets that claimed limitation of "effective dose" absent any recitation of dose. Although applicants feel strongly that the prior art rejection must address the integral property of the invention, Examiner maintains that property is addressed as being inherent as admitted by applicants. The property of a system or composition cannot be separated from the composition/system. Applicants provided no data to indicate that the broad system disc of the instant claims differs compositionally from the prior art apart from applicants' assertion of an inherent property. Question: Why must a disc or system that comprises a filmogenic polymer and an active agent dissolve on a wetted/wet skin and a prior art system/device that comprises a filmogenic polymer and an active agent not dissolve on a wetted/wet skin? The instant method is an administration process and the prior art administers and administration meets the limitation of administration. The instant claims cannot exclude the presence of chitosan in the prior art

because the generic claim that is a comprising limitation. Examiner agrees with applicants that Lorenz uses the gels as absorbent wound packing agents that become saturated with wound exudates. However, it is respectfully noted that column 2, lines 39-44 of Lorenz disclose that gel can be used in other applications and that the gels may be tacky or non-tacky. Thus there are several embodiments to gel of Lorenz. For example, Lorenz's product can be packaged as a dry film. The important observation is that applicants provided no compositional differences between the generic invention and the prior art. Lorenz's gels are hydrophilic.

3. Claims 1, 3 and 21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Leonard et al. (US 4,820,525).

Applicants argue that instant claim 1 recites a delivery disc that contains a filmogenic polymer and an effective dose of an active substance; the delivery disc is non-tacky and of a single uniform layer. Applicants further argue that claim 21 recites a method of administering active substance to a subject and the method comprises application of the delivery disc to a mucosal epithelial layer and the delivery disc dissolves after application. Applicants also argue that the system of Leonard is a foam, which does not dissolve after a 24-hour period.

4. Applicants' arguments filed 07/19/04 have been fully considered but they are not persuasive.

The instant generic claim does not state how long the disc is left before it dissolves and more importantly, as recognized by applicants, dissolution is an integral property of the disc. 24-hour period is not excluded by the instant claims. What happens to the claimed disc at 24 hours? There is no demonstration that compositions that are essentially the same have different properties. Applicants provided no explanation why two identical compositions would have

different properties. The instant filmogenic polymer is not named and the active agent is not named. The filmogenic polymer and the active agent of the prior art meet the limitations of the instant generic claims and thus would have the property inherent or integral to the composition/system. Applicants' insistence on the integral property of the disc appears to suggest that there may be compositional difference that has not been disclosed or claimed. The instant claims as recited do not provide compositional difference or method that is other than application or administration.

Claim Rejections - 35 USC § 103

5. Claims 10-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lorenz et al. (US 5,420,197).

Applicants continue to argue the inherent integral dissolution property of the disc and maintain that Lorenz does not expressly disclose dissolution but rather discloses that the gel does not dissolve or disintegrate in large amounts of water and that Lorenz does not render the claims obvious because Lorenz does not suggest the limitations of the claims.

Generic claim 1 is directed to a broad delivery disc that comprises a dry uniform mixture a filmogenic polymer and an effective dose of an active agent. This is the composition of the delivery system/disc. The generic claim fails to specify any polymer. The generic claim fails to specify active agent and effective dose. Regarding the active agent and effective dose, any active agent meets the limitation of the recited "active agent" and any dose of an active agent is effective and meets that claimed limitation of "effective dose" absent any recitation of dose. The property of a system or composition cannot be separated from the composition/system. Applicants provided no data to indicate that the broad system disc of the instant claims differs

compositionally from the prior art apart from applicants' assertion of an inherent property. Question: Why must a disc or system that comprises a filmogenic polymer and an active agent dissolve on a wetted/wet skin and a prior art system/device that comprises a filmogenic polymer and an active agent not dissolve on a wetted/wet skin? The instant method is an administration process and the prior art administers and administration meets the limitation of administration.

Double Patenting

Applicants acknowledge the provisional rejection of claims 1, 3, 6, 8 and 15 under the judicially created doctrine of obviousness-type double patenting and requests the rejection to be held in abeyance until an allowable subject matter is identified. However, applicants agree with Examiner that the rejection should continue to be made. Thus the obviousness-type double patenting rejection is maintained.

6. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose acne agents.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BF

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